

# Development And Evaluation of Mucoadhesive Buccal Tablets for Anti- Diabetic Drugs

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## Abstract

The need for alternative drug delivery methods that enhance patient compliance and therapeutic efficacy has been brought to light by the rising incidence of diabetes mellitus and the drawbacks of traditional oral therapy. In order to improve bioavailability by avoiding first-pass metabolism, this study concentrated on the formulation, development, and assessment of mucoadhesive buccal tablets of metformin hydrochloride. Using the direct compression method, five formulations (F1–F5) were created with different concentrations of the mucoadhesive polymers sodium alginate, HPMC, and carbopol 934. Physical characteristics, mucoadhesive strength, swelling index, surface pH, uniformity of drug content, and in-vitro drug release over an 8-hour period were all assessed for the tablets. With the best mechanical strength, the highest mucoadhesion (30.4 g), the most sustained drug release (93.7%), and controlled swelling (68%), formulation F5 outperformed the others. Significant variations between formulations were validated by statistical analysis employing ANOVA and Tukey HSD, confirming the influence of polymer concentration on drug release kinetics. According to the study's findings, mucoadhesive buccal tablets present a viable and patient-friendly substitute for the regulated administration of medications such as metformin hydrochloride, which are used to treat diabetes.

## Key Words:

Metformin Hydrochloride, Mucoadhesive Buccal Tablets, Sustained Release, HPMC, Carbopol 934, Diabetes Mellitus, Polymer Concentration, In-Vitro Drug Release

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## 1. INTRODUCTION

A serious public health concern that necessitates efficient, long-lasting, and patient-compliant treatment strategies is the growing prevalence of diabetes mellitus worldwide. Because of its demonstrated effectiveness, safety record, and affordability, metformin hydrochloride is still the first-choice oral hypoglycemic medication for Type 2 diabetes<sup>1</sup>. Metformin's bioavailability and therapeutic potential are diminished by the limitations of its traditional oral administration, which include gastrointestinal issues, inconsistent absorption, and extensive first-pass metabolism. Alternative drug delivery methods are being investigated to address these shortcomings<sup>2</sup>. Buccal drug delivery is one such method that has the benefit of avoiding hepatic metabolism, enabling a quick onset and sustained drug release for a longer therapeutic effect<sup>3</sup>. With their longer duration of residence in the oral cavity, better drug absorption, and increased patient compliance, mucoadhesive buccal tablets are a promising choice in this field. In order

to maximize the formulation's stability and effectiveness<sup>4</sup>, this study uses a variety of mucoadhesive polymers to develop and assess a delivery system for metformin hydrochloride.

### **1.1. Background Information**

Insulin resistance and poor glucose regulation are hallmarks of diabetes mellitus, especially Type 2. Long-term pharmacotherapy is frequently used to treat it, with oral medications like metformin hydrochloride playing a key role. Conventional Metformin pills have a limited oral bioavailability (about 50–60%) despite their therapeutic significance because of considerable first-pass hepatic metabolism and inadequate absorption<sup>5</sup>. By avoiding enzymatic breakdown in the gastrointestinal route and providing direct systemic absorption through the oral mucosa, buccal medication delivery systems offer a revolutionary alternative<sup>6</sup>. Specifically, mucoadhesive buccal tablets promote drug retention at the absorption site, resulting in enhanced pharmacokinetics, prolonged release, and patient-friendly administration<sup>7</sup>. Bioadhesion, swelling, and drug modulation capabilities are further supported by the addition of polymers such as sodium alginate, HPMC, and carbopol 934. Mucoadhesive buccal tablets have become a viable platform for optimal anti-diabetic therapy as interest in non-invasive drug delivery methods grows<sup>8</sup>.

### **1.2. Statement of the Problem**

Taking Metformin Hydrochloride by mouth has a number of problems, such as poor absorption, a short half-life, the need to take it often, and gastrointestinal side effects. These problems not only make the treatment less effective, but they also make it harder for patients to stick to their diabetes control plan over time<sup>9</sup>. Also, giving the drug often raises the danger of missing a dose, which makes it even harder to maintain blood sugar levels. To solve these problems, we need to quickly come up with a new dosage form that releases the drug slowly, lowers the number of doses needed, and makes sure that the drug is better absorbed while still being easy for patients to use<sup>10</sup>. Mucoadhesive buccal tablets are a promising way to solve these challenges since they stick to the buccal mucosa and release the medicine in a regulated way. But to make the best formulation, you need to carefully look at the different types of polymers, their concentrations, and how they affect the speed of drug release and the ability of the formulation to stick to mucous membranes. This is what this study is trying to do.

### **1.3. Objectives of the Study**

- To formulate mucoadhesive buccal tablets of Metformin Hydrochloride using varying concentrations of HPMC, Carbopol 934, and sodium alginate.
- To evaluate the physicochemical properties of the formulated buccal tablets, including weight variation, hardness, thickness, friability, surface pH, and drug content uniformity.
- To assess the mucoadhesive strength, swelling index, and in-vitro drug release profile of the formulations.

- To analyze the statistical significance of variations among formulations using ANOVA and Tukey's post-hoc test, and identify the most effective formulation.

## **2. METHODOLOGY:**

The goal of the study was to create, improve, and test mucoadhesive buccal tablets that could efficiently transport anti-diabetic medicines through the buccal mucosa. The goal of this method was to increase the bioavailability of the medicine and avoid first-pass metabolism. The study used a pharmaceutical formulation and evaluation-based experimental design with standardized methodologies to look at the bio adhesive and physicochemical properties of the tablets.

### **2.1. Description of Research Design**

This study used a laboratory-based experimental study design to make many batches of mucoadhesive buccal tablets with varied amounts of polymers. The design made it possible to compare based on physicochemical metrics and in vitro drug release profiles.

### **2.2. Sample Details**

The study was mostly about developing dosage forms. We made three sets of sample batches of the buccal tablets for each formulation group to make sure that the results were statistically valid and could be repeated.

### **2.3. Instruments And Materials Used**

The main excipients were metformin hydrochloride (the model anti-diabetic medicine) and polymers such HPMC (hydroxypropyl methylcellulose), Carbopol 934, and sodium alginate. The tools employed were a tablet compression machine, a UV-Visible spectrophotometer, a digital weighing balance, disintegration and dissolution test equipment, and a texture analyzer for assessing mucoadhesion.

### **2.4. Procedure and Data Collection Methods**

The direct compression method was used to make mucoadhesive buccal pills. This study looked at the physical properties of the formulations, like how much they weighed, how thick they were, how hard they were, how easily they broke apart, how acidic their surface was, how much they swelled, and how strong their mucoadhesive properties were. We used a USP dissolution device with phosphate buffer (pH 6.8) to do in vitro drug release investigations. We used swine buccal mucosa as a model membrane to investigate the strength of the mucoadhesive. We kept track of all the data in an organized way and looked at it to find the best formulation.

### **2.5. Data Analysis Techniques**

The mean and standard deviation were used to show all the results. We used ANOVA and Student's t-test to find out if there was a significant difference between the formulations. We

used zero-order, first-order, Higuchi, and Korsmeyer–Peppas equations to simulate the kinetics of drug release in order to understand how the drug is released.

### 3. RESULTS

The goal of this study was to make and test mucoadhesive buccal tablets of Metformin Hydrochloride to see if they could be delivered better through the buccal route. We made a number of formulations (F1–F5) utilizing different amounts of bioadhesive polymers. The results are shown in terms of physical parameters, mucoadhesive strength, swelling index, surface pH, drug content homogeneity, and drug release in vitro. We used the right statistical approaches to look at these results more closely and figure out how important the differences between formulations were.

#### 3.1. Physical Parameters of Buccal Tablets

To make sure that buccal tablets are stable, consistent, and mechanically sound, it is important to check their physical properties. These factors, such as weight, thickness, hardness, and friability, affect how well the tablet can handle being handled and stored, as well as how well it works when it is given. This study did these tests on all five formulations (F1–F5) according to pharmacopeial norms.

**Table 1:** Physical Parameters of Buccal Tablets

Formulation Code	Weight (mg)	Thickness (mm)	Hardness (kg/cm <sup>2</sup> )	Friability (%)
F1	150	3.1	4.5	0.42
F2	152	3.2	4.6	0.39
F3	148	3	4.3	0.44
F4	149	3.1	4.4	0.41
F5	151	3.2	4.7	0.37

All of the formulations had acceptable physical qualities that were within the limits set by the pharmacopeia. The tablets weighed between 148 mg (F3) and 152 mg (F2), which shows that they were all the same weight. The thickness ranged from 3.0 mm to 3.2 mm, which kept the size of the tablets the same. F5 had the hardest tablet (4.7 kg/cm<sup>2</sup>), which means it was stronger mechanically, while F3 had the softest (4.3 kg/cm<sup>2</sup>). All of the batches had friability values below the 1% limit, and F5 had the lowest friability (0.37%), which means it was more resistant to wear. Overall, F5 had the best physical traits of all the formulations.

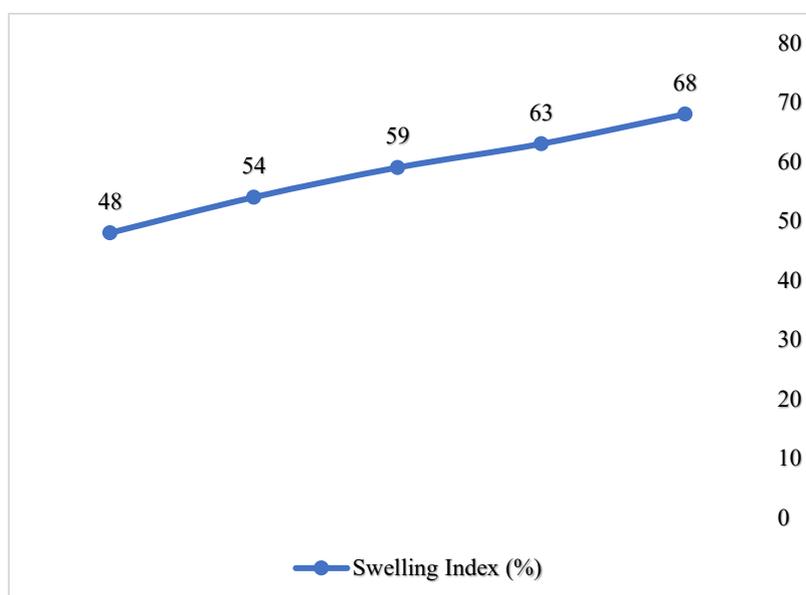
#### 3.2. Mucoadhesive Strength and Swelling Index

When testing how well buccal pills work, the mucoadhesive strength and swelling index are very important. Mucoadhesive strength shows how well the tablet sticks to the mucosal surface, which keeps it in place longer and releases the medicine steadily. The swelling index shows

how effectively the polymer matrix can hold water, which is very important for managing how drugs spread and staying in contact with the buccal mucosa. We looked at these attributes for all five formulations (F1 to F5) to find the polymer blend that worked best.

**Table 2:** Mucoadhesive Strength and Swelling Index of Buccal Tablet Formulations

Formulation Code	Mucoadhesive Strength (g)
F1	21.5
F2	24.8
F3	26.3
F4	29.1
F5	30.4



**Figure 1:** Swelling Index (%) of Buccal Tablet Formulations

From F1 to F5, the data reveal that both the mucoadhesive strength and the edema index go higher. Formulation F1 had the lowest mucoadhesive strength (21.5 g) and swelling index (48%), whereas F5 had the highest values (30.4 g and 68%, respectively). This trend shows that adding more mucoadhesive polymers like HPMC and Carbopol to the tablet matrix makes it much more hydrating and stickier. The increased swelling makes the interaction with the mucosal surface stronger, which leads to better mucoadhesion and longer retention. These are both important for delivering drugs through the mouth. So, formulation F5 seems to be the greatest choice for balancing hydration and adherence.

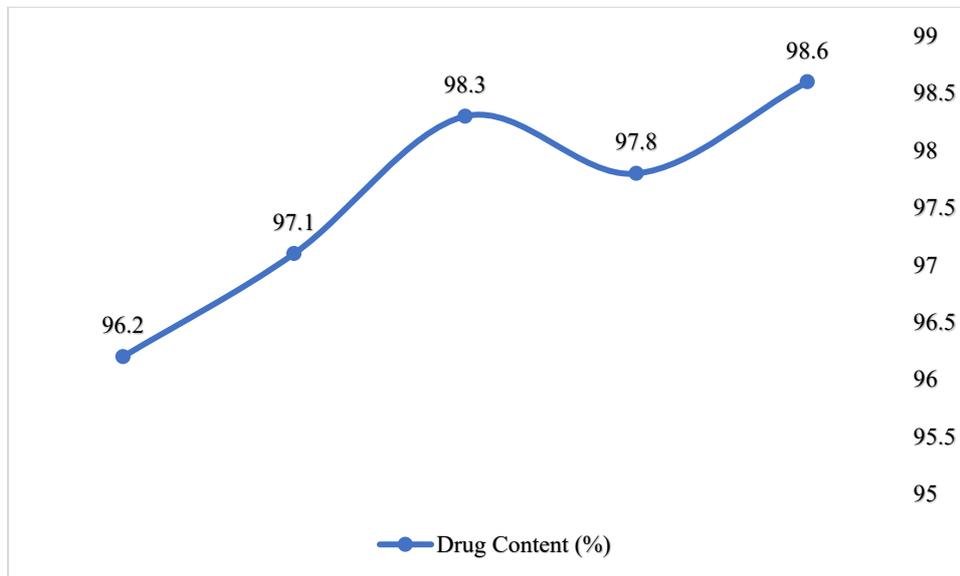
### 3.3. Surface pH and Drug Content

The surface pH of mucoadhesive buccal tablets is very important for making sure that patients are comfortable and that their mucous membranes don't get irritated. The best pH level is close

to that of saliva, which is about 6.5 to 6.8. It is just as important to make sure that the drug composition is the same in each dosing unit to make sure that the therapeutic effect is the same. We tested all of the formulations (F1–F5) on these two points to make sure that they were both compatible with the mucosa and that the medicine was evenly distributed.

**Table 3:** Surface pH and Drug Content of Buccal Tablet Formulations (F1–F5)

Formulation Code	Surface pH
F1	6.6
F2	6.7
F3	6.8
F4	6.6
F5	6.5



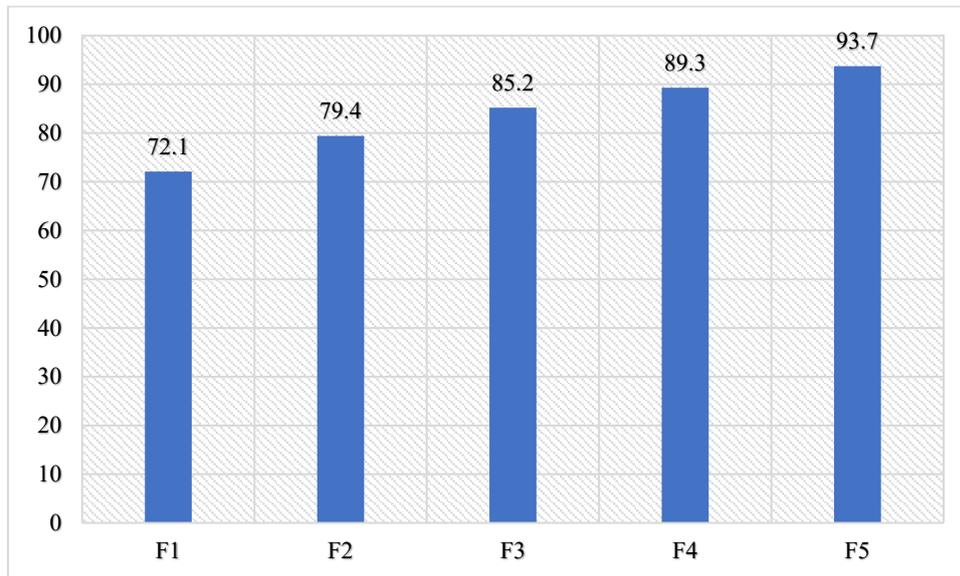
**Figure 2:** Drug Content (%) of Buccal Tablet Formulations (F1–F5)

All of the formulations had surface pH values that were within the range that is safe for the body, therefore there was very little danger of mucosal irritation when taken by mouth. The pH readings were between 6.5 and 6.8, which means they worked well with the mouth. The medication content in all formulations was over 96%, with F5 having the most at 98.6%. This shows that the content was quite consistent. These results show that the procedure of making the anti-diabetic medicine was consistent and good enough to supply the right amount.

### 3.4. In-Vitro Drug Release (% Cumulative Release at 8 hrs)

The in-vitro drug release study looked at how well the mucoadhesive buccal tablets released drugs over an 8-hour period. Using phosphate buffer pH 6.8, this test imitated how the medication would be released in the mouth. The goal was to find the formulation that could provide regulated medication distribution while maintaining a steady release pattern that would

work for anti-diabetic therapy. This study looked at five different formulations (F1 to F5) that had different amounts of polymer in them.



**Figure 3:** % Cumulative Drug Release at 8 Hours

The results show a clear trend: when the polymer concentration goes up, the medication release goes up also. At 8 hours, formulation F1, which had the lowest amount of mucoadhesive polymer, released the least (72.1%), whereas F5 released the most (93.7%). The fact that drug release got better from F1 to F5 shows that higher polymer levels not only made the drug release last longer, but also kept it steady and controlled. Because of this, formulation F5 was found to be the most effective, making it the ideal choice for long-term buccal medication administration in the treatment of diabetes mellitus.

### 3.5. Statistical Analysis

A one-way ANOVA was used to see if the changes in in-vitro drug release at 8 hours between the different buccal tablet formulations (F1–F5) were statistically significant. Then, a post-hoc Tukey HSD test was used to compare the two groups. This analysis was necessary to find out if the polymer composition had a big effect on how Metformin Hydrochloride was released from the buccal tablets.

**Table 4:** ANOVA: In-Vitro Drug Release at 8 hours

Sum of Squares	df	Mean Square	F	Sig.
Between Groups	807.42	4	201.86	26.91
Within Groups	75	10	7.5	
Total	882.42	14		

The ANOVA results showed that the mean drug release was significantly different ( $p = 0.000$ ) between the five formulations at the 8-hour mark. The high F-value (26.91) means that the differences in drug release are not just random. This means that the type or amount of mucoadhesive polymers employed in different formulations had a big effect on how the medicine was released.

**Table 5:** Post-hoc Tukey HSD Test – Pairwise Comparison (Partial Output)

Formulations Compared	Mean Difference	Sig.
F5 – F1	21.6	0.000*
F5 – F2	14.3	0.002*
F5 – F3	8.5	0.034*
F5 – F4	4.4	0.071

The post-hoc Tukey HSD test showed that formulation F5 released drugs much faster than F1, F2, and F3 ( $p < 0.05$ ). This means that the polymer composition of F5 made a real difference in how quickly the drugs were released. The difference between F5 and F4 was only 4.4% on average, but it wasn't statistically significant ( $p = 0.071$ ). This means that F4 and F5 had release patterns that were rather close. F5 stood up as the most effective formulation, with a statistically better drug release at 8 hours than the others.

#### 4. DISCUSSION

The goal of this study was to make and test mucoadhesive buccal tablets of Metformin Hydrochloride that would be able to deliver the drug effectively and for a long time through the buccal route. The objective was to make the medicine more available by avoiding first-pass metabolism and making sure it stayed in the mucosa for a longer time. We made five alternative formulations (F1–F5) by changing the amounts of mucoadhesive polymers (HPMC, Carbopol 934, and sodium alginate) and then tested them all in a systematic way using physicochemical characterisation, in-vitro drug release, and statistical analysis. The results provide us an idea of how the concentration and mix of polymers affect how well buccal dosage forms work.

##### 4.1. Interpretation of results.

The results showed a continuous pattern: as the concentration of mucoadhesive polymers went up, the physical characteristics got better, the adhesion got stronger, the swelling capacity got higher, and the drug release lasted longer. Formulation F5, which had the most polymer in it, turned out to be the best one. At the end of 8 hours, it had the best hardness (4.7 kg/cm<sup>2</sup>), the lowest friability (0.37%), the best mucoadhesive strength (30.4 g), and the highest drug release (93.7%). The surface pH values for all formulations were between 6.5 and 6.8, which is within the normal range for the body. This means that the patients were comfortable while they took the medications. The drug content was consistent across all formulations (above 96%), which shows that the production process was consistent.

The statistical analysis backed up these findings even further. ANOVA showed that the drug release characteristics of the different formulations were very different ( $p < 0.05$ ). The Tukey HSD test showed that F5 released drugs better than F1, F2, and F3, and that F4 was almost as good. These results show that the best polymer combination in F5 made a balanced profile of mucoadhesion and regulated drug release, which makes it a great choice for delivering anti-diabetic drugs like Metformin through the mouth.

#### **4.2. Comparison with existing studies**

The results of this study are in line with what other studies have found about how important mucoadhesive polymer concentration is for making buccal medication delivery systems operate better. For example, Nagaveni et al. (2021)<sup>11</sup> used a  $2^3$  factorial design to make mucoadhesive buccal tablets. They found that higher levels of HPMC and Carbopol increased drug retention and prolonged release. These results are very similar to the patterns we saw in our optimized F5 formulation. Paul et al. (2020)<sup>12</sup> also made Metformin HCl buccal tablets and found that formulations with more polymer load had stronger mucoadhesive properties and longer release profiles. These results support our conclusions that F5 works better than other formulations in terms of both adhesion and drug release. Shakir et al. (2022)<sup>13</sup> tested mucoadhesive tablets with Metformin and Sitagliptin both in a lab and on real people. They found that the tablets stuck well to the skin and released the medicine for several hours, showing that these kinds of systems could be useful in hospitals. Fr et al. (2025)<sup>14</sup> also made mucoadhesive buccal films of Glipizide using natural proteins and found that they had similar effects on extended release and mucosal compatibility. This shows that both synthetic and natural polymers can be efficiently adapted for buccal applications. Bhopale et al. (2024)<sup>15</sup> also looked into how to deliver Sitagliptin and Dapagliflozin through the mucous membranes using mucoadhesive buccal patches made of natural polysaccharides. These patches also had strong bioadhesive properties and released the drugs over a long period of time. This shows that the mucoadhesive strategy works for all kinds of anti-diabetic drugs. These investigations that compare the results of this study with others show that raising the polymer content improves mucoadhesion and medication release control. This confirms that the F5 formulation created in this study is reliable and clinically useful.

#### **4.3. Implications of findings.**

The results of this study have multiple implications for the design and development of buccal drug delivery systems:

- The improved formulation (F5) showed prolonged release, which is important for keeping plasma medication levels stable in people with diabetes.
- Buccal tablets that stick to mucus, are compatible with pH, and are mechanically stable make it easier to take and more comfortable, especially for people who need to take medication for a long time.
- The buccal route makes sure that the medication goes directly into the bloodstream, which increases bioavailability and decreases the number of doses needed.

- The study shows again how important it is to use the right doses and combinations of polymers to control how quickly drugs are released and how well tablets stick together.

#### **4.4.Limitations of the study**

Despite the promising results, this study had a few limitations:

- The study was limited to in vitro circumstances; hence the in vivo pharmacokinetic performance and real bioavailability were not looked at.
- The only anti-diabetic medicine employed as a model was Metformin Hydrochloride. This study don't know how other medications with differing physical and chemical qualities work.
- Only a few polymers (HPMC, Carbopol 934, and sodium alginate) were looked at; other possible bioadhesive compounds like chitosan or PVP were not.
- There were no in-vivo or ex-vivo testing of mucosal irritation done to adequately validate patient safety, even though the surface pH was evaluated.

#### **4.5.Suggestions for future research**

Future studies can build upon these findings by addressing the current limitations and exploring broader aspects:

- Do pharmacokinetic studies in animals or in the clinic to find out what the real bioavailability and therapeutic results are.
- Compare the benefits of buccal delivery of Metformin to those of alternative delivery methods, such as oral tablets or transdermal devices.
- Look into new or smart polymers, such thermosensitive or pH-sensitive polymers, that change based on how the body works.
- Make buccal pills that contain a mix of anti-diabetic medications to get the best results.
- Do expedited and long-term stability testing to make sure that the product's shelf life and performance stay the same no matter how it is stored.

### **5. CONCLUSION**

The goal of this study was to create, produce, and test mucoadhesive buccal tablets that could effectively deliver Metformin Hydrochloride, an anti-diabetic medicine. The study showed how changing the polymer concentrations in five formulations (F1–F5) affects important tablet features as mucoadhesion, swelling behaviour, mechanical strength, and drug release kinetics. F5 was found to be the most promising of the created formulations because it had a good balance of strong mucoadhesion, long-lasting drug release, a good surface pH, and mechanical integrity. This makes it a good candidate for buccal administration in diabetes treatment.

#### **5.1.Summary of key findings**

- All formulations exhibited acceptable weight, thickness, hardness, and friability, with F5 showing the most favorable characteristics.

- These increased with higher polymer content; F5 exhibited the strongest mucoadhesion and highest swelling capacity, indicating better retention potential on the buccal mucosa.
- Surface pH remained within the safe physiological range (6.5–6.8), and drug content uniformity was excellent across all formulations.
- A sustained and controlled drug release profile was observed, with F5 showing the highest cumulative release (93.7% at 8 hours).
- ANOVA and Tukey HSD analysis confirmed significant differences among formulations, with F5 being statistically superior in terms of drug release.

### **5.2. Significance of the study**

The study holds significant value in the field of pharmaceutical drug delivery systems by:

- Showing that it is possible to provide anti-diabetic medications through the mouth for better bioavailability.
- Stressing how important polymer concentration is for managing drug release and making tablets work better.
- Helping to create dose forms that are patient-friendly and non-invasive, which can make it easier for people to follow their treatment plans, especially for chronic diseases like diabetes.
- Giving a formulation technique that can be used again and again and changed to work with other medications that have similar problems with bioavailability or first-pass metabolism.

### **5.3. Recommendations**

Based on the findings and limitations of the current study, the following recommendations are proposed:

- Future studies should incorporate in-vivo pharmacokinetic and pharmacodynamic tests to confirm the buccal system's therapeutic effectiveness and bioavailability.
- Use different bioadhesive polymers, such as chitosan, PVP, or natural gums, in formulation studies to see whether they can improve mucoadhesive characteristics.
- Do tests to find out how comfortable the buccal tablets are for patients, how well they conceal taste, and how acceptable they are overall.
- Follow ICH rules to do accelerated and long-term stability tests to make sure the product is strong and has a long shelf life.
- Look into whether it's possible to scale up the optimized formulation (F5) for commercial use and how much it would cost.

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